

## Message Text

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62

ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-06 EB-07 COME-00 CIAE-00  
INR-07 NSAE-00 /036 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

APPROVED BY OES/OPT/BMP: JFRY

DHEW/OIH: BROYSTER

EA/ANP:HTNELSON(INFO)

----- 036004

P 072347Z DEC 76

FM SECSTATE WASHDC

TO AMCONSUL SYDNEY PRIORITY

INFO AMEMBASSY CANBERRA PRIORITY

UNCLAS STATE 297869

E.O. 11652: N/A

TAGS: BEXP, TBIO, AS

SUBJECT: U.S. ACCEPTANCE OF YELLOW PHENOPHTHALEIN

REF: SYDNEY 3009

1. FDA ADVISES THAT:

(A) THE UNITED STATES PHARMACOPEIA (USP) XIX REVISION  
LISTS PHENOPHTHALEIN AS AN INDICATOR. INDICATORS ARE RE-  
QUIRED IN THE PHARMACOPEIAL TESTS AND ASSAYS EITHER TO  
INDICATE THE COMPLETION OF A CHEMICAL REACTION IN VOLU-  
METRIC ANALYSIS OR TO INDICATE THE HYDROGEN-ION CONCEN-  
TRATION (PH) OF A SOLUTION.

(B) THE NATIONAL FORMULARY (N.F.) - 14TH EDITION LISTS  
PHENOPHTHALEIN AS A CATHARTIC. THE DESCRIPTION SECTION  
OF THE MONOGRAPH STATES, "PHENOPHTHALEIN OCCURS AS A WHITE  
OR FAINTLY YELLOWISH WHITE, CRYSTALLINE POWDER." THE  
SECTION, COLOR OF SOLUTION STATES, , A SOLUTION OF 500 MG  
OF PHENOPHTHALEIN IN 30 ML OF ALCOHOL HAS NO MORE COLOR  
THAN MATCHING FLUID A." THIS IS A COLOROMETRIC STANDARD  
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WHICH INDICATES THE LIMIT OF ACCEPTABILITY OF PHENO-

PTHALEIN, IN SO FAR AS COLOR IS CONCERNED, AS A COMPENDIAL  
DRUG.

NEITHER U.S.P. OR N.F. HAVE RECEIVED PROPOSALS FOR  
"YELLOW PHENOPHTHALEIN." ANY COLOR OTHER THAN THAT PRE-  
SCRIBED BY N.F. WOULD RENDER DRUG PRODUCT ADULTERATED  
UNDER SECTION 501(B) OF THE FEDERAL FOOD, DRUG AND COSMETIC  
ACT, AS AMENDED.

3. SUGGEST BRITISH MEDICAL INDUSTRIES MAY WISH TO COR-  
RESPOND WITH DR. DANIEL BANES, UNITED STATES PHARMACOPEIAL  
CONVENTION, 12601 TWINBROOK PARKWAY, ROCKVILLE, MARYLAND  
20852. ROBINSON

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** DRUGS, FOOD & DRUG REGULATIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 07 DEC 1976  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1976STATE297869  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.:CCK  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D760452-1237  
**From:** STATE  
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**Line Count:** 74  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
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**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
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**Review Authority:** wolfsd  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 01 JUN 2004  
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**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** U.S. ACCEPTANCE OF YELLOW PHENOPHTHALEIN  
**TAGS:** BEXP, TBIO, AS, FDA  
**To:** SYDNEY  
**Type:** TE  
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